JOHN ENGLER, Governor

DEPARTMENT OF COMMUNITY HEALTH

JAMES K. HAVEMAN, JR., Director

COMMUNITY PUBLIC HEALTH ADMINISTRATION

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November 30, 2000

Dockets Management Branch, HFA-305 Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Subject: Comments on the Food and Drug Administration's Proposed Labeling

Requirements for Systemic Antibacterial Drug Products Intended for Human

Use

Docket Number: 00N-1463

Dear Sir or Madam,

The Communicable Diseases Epidemiology and Immunization Division and the Bureau of Laboratories of the Michigan Department of Community Health (MDCH) welcomes the Food and Drug Administration (FDA) proposal that all systemic antibacterial drug products intended for human use contain additional labeling information about the emergence of drug-resistant bacterial strains. We support adoption of this proposed rule and feel that education of health care practitioners is an important first step in more appropriate use of antimicrobial agents by health care workers in this country.

We anticipate that similar statements will eventually be included in the labels of antiparasitic, antiviral, antifungal, antimycobacterial, as well as topical antibacterials and topical antiseptics. While recognizing that labeling of each of these types of agents presents unique challenges, clearly development of resistance to each of these agents is a real or potential problem which may be aggravated by inappropriate use.

Regulatory actions have the potential of impacting in a positive way on the problem of antimicrobial resistance. The Michigan Department of Community Health encourages continued FDA consultation with the public health community at both the federal and state level as the agency evaluates new antimicrobial agents. It is our hope that the labeling process may be used in a manner which promotes maintenance of the efficacy of narrow spectrum drugs targeted against resistant organisms. The Michigan Department of Community Health applauds the spirit and action of the proposed rule, and we support its finalization.

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Sincerely,

Dus .- D Carry J. M.D.

Susan D. Thompson, M.D.

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